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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/806,639	05/21/2001	Doris Hueblér	1565	3031

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Michael J Striker
103 East Neck Road
Huntington, NY 11743

EXAMINER

CHANNAVAJJALA, LAKSHMI SARADA

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 07/30/2002 7

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/806,639

Applicant(s)

HUEBLER ET AL.

Examiner

Lakshmi S Channavajjala

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-6 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-6 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). ____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5, 6. 6) ☐ Other:

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DETAILED ACTION

Receipt of declaration, dated 5-21-01, Information Disclosure Statements, dated 6-15-01 and 5-21-01 is acknowledged.

1. Examiner notes that a simultaneous amendment, dated 4-2-01, has been filed along with the application, requesting cancellation of all the claims and substituting them with the amended claims. However, the claims presented in this amendment are not in English language (37 CFR 1.52). Accordingly, the claims have not been entered.

Status of Claims

2. Claims 1-6 are presented.

Specification

3. The abstract of the disclosure is objected to because it is present in two paragraphs. Applicant is reminded of the proper language and format for an abstract of the disclosure. The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. Appropriate correction is required. See MPEP § 608.01(b).

4. Examiner notes that the instant title is lengthy. The title of the invention should be brief but technically accurate and descriptive; preferably from two to seven words may not contain more than 500 characters. See 37 CFR 1.72(a) and MPEP § 606. Further, it is observed that the specification contains subject matter in parentheses at several instances. It is requested that the specification is checked to delete the parentheses, as appropriate.

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5. Examiner notes that the specification does not contain a Brief description of drawings. A reference to and brief description of the drawing(s) as set forth in 37 CFR 1.74 is required. See MPEP § 608.01(f).

Claim Objections

6. Claims 4 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For examination purposes claim 4 has been treated as being dependent on claim 1.

7. Claims 6 is objected to under 37 CFR 1.75(c) as being in improper form because a multiple dependent claim should refer to other claims in the alternative only. See MPEP § 608.01(n). For examination purposes claim 4 has been treated as being dependent on claim 1.

8. Claim 5 is objected as being in improper form because the claim is dependent upon a multiple dependent claim. However, as explained in item 6, claim 4 has been treated as being dependent upon claim 1. Appropriate correction of claim dependencies is requested.

Claim Rejections - 35 USC § 112

9. Claims 1-6 provide for the use of testosterone esters, but, since the claim does not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

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Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed recitation of a use, without setting forth any steps involved in the process, results in an improper definition of a process, i.e., results in a claim which is not a proper process claim under 35 U.S.C. 101. See for example *Ex parte Dunki*, 153 USPQ 678 (Bd.App. 1967) and *Clinical Products, Ltd. v. Brenner*, 255 F. Supp. 131, 149 USPQ 475 (D.D.C. 1966).

10. Claim 6 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim is indefinite for the recitation of "tailored manner" because the claimed term has not been defined in the specification. Accordingly, it is unclear as how applicants intend attain a therapeutic level of testosterone for treating circadian rhythm. For examination purposes, "tailored manner" is considered as attaining blood level patterns of testosterone such that they are capable of recreating or stimulating body's own rhythmicity of endogenous testosterone levels.

11. A broad range or limitation together with a narrow range or limitation that falls within the broad range or limitation (in the same claim) is considered indefinite, since the resulting claim does not clearly set forth the metes and bounds of the patent protection desired. Note the explanation given by the Board of Patent Appeals and Interferences in *Ex parte Wu*, 10 USPQ2d 2031, 2033 (Bd. Pat. App. & Inter. 1989), as to where broad language is followed by "such as" and then narrow language. The Board stated that this can render a claim indefinite by raising a question or doubt as to whether the feature introduced by such language is (a) merely

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exemplary of the remainder of the claim, and therefore not required, or (b) a required feature of the claims. Note also, for example, the decisions of *Ex parte Steigewald*, 131 USPQ 74 (Bd. App. 1961); *Ex parte Hall*, 83 USPQ 38 (Bd. App. 1948); and *Ex parte Hasche*, 86 USPQ 481 (Bd. App. 1949). In the present instance, claim 3 recites the broad recitation 1:100 to 1:1, and the claim also recites preferably from 1:10 to 1:5 which is the narrower statement of the range/limitation.

Claim Rejections - 35 USC § 101

12. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-6 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Instant claims merely recite the use of testosterone for treating diseases associated with modified testosterone levels. However, the claims do not recite any steps as to how the composition is used. Accordingly, the claimed subject matter is non-statutory. For the purpose of examination, the claims are interpreted as a method of treating diseases associated with modified testosterone levels using a composition comprising testosterone esters.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

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(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

13. Claims 1, 2 and 4-6 are rejected under 35 U.S.C. 102(b) as being anticipated by Voorspoels et al (submitted on PTO-1449, hereafter "Voorspoels").

As explained above (35 USC 101), instant claims are interpreted as a method of treating diseases associated with modified testosterone levels by buccal administration of a composition comprising testosterone esters.

Voorspoels discloses bioadhesive tablets comprising testosterone and its esters for buccal administration. Testosterone and its esters i.e., acetate, propionate, enanthate and decanoate disclosed by Voorspoels meet the claim requirement of testosterone esters with 1-20 carbon atoms in the carboxylic acids radical (page 1228, col. 2, 1st paragraph and table 1).

Claims 4 and 5 recite the process of making buccal bioadhesive system. Voorspoels does not specifically teach the claim limitations. However, because the instant claims are interpreted as method of treatment by buccal administration of testosterone and its esters, the process of preparing the buccal tablets, does not carry patentable weight. Accordingly, the irrespective of the claimed process making the tablet, Voorspoels anticipates the claimed method of treatment. Voorspoels disclose that the bioavailability of testosterone is higher with buccal administration as compared to oral administration (page 12-30, col. 1, 2nd paragraph). Thus, it is inherent in the teachings of Voorspoels that buccal administration of testosterone attains therapeutic levels, as required by claim 6.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 3 rejected under 35 U.S.C. 103(a) as being unpatentable over Voorspoels et al (Voorspoels).

Instant claim recites that the ratio of testosterone to its esters is from 1:100 to 1:1. Voorspoels teaches buccal administration of testosterone and testosterone esters, but fails to teach a combination. However, it would have been obvious for one of an ordinary skill in the art at the time of the instant invention to combine testosterone and its esters of Voorspoels in one composition and administer them via buccal route because Voorspoels teaches these compounds independently for simulating the circadian rhythm of testosterone plasma levels. It is obvious to combine two compositions taught by prior art to be useful for the same purpose to form a third composition that is to be used for the very same purpose to form a third composition to be useful for the very same purpose. In re Kerkhoven, 626 F.2d 846, 205 USPQ 1069 (CCPA 1980). Accordingly, one of an ordinary skill in the art would have expected to achieve an additive effect in simulating circadian rhythm by combining testosterone and esters of testosterone.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lakshmi S Channavajjala whose telephone number is 703-308-2438. The examiner can normally be reached on 7.30 AM -4.00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-7924 for regular communications and 703-308-7924 for After Final communications.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

A handwritten signature in black ink, appearing to read 'Lakshmi S Channavajjala', written over a horizontal line.

Lakshmi S Channavajjala

Examiner

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July 29, 2002